Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LATA RAMANTHAN[1], GAIL F. SEELIG and PAUL P. TROTTA

Appeal No. 1997-0711
Application No. 08/271,539[2]

ON BRIEF

Before WINTERS, SPIEGEL, and MILLS, Administrative Patent Judges.

SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner finally rejecting claims 12 and 13 and refusing to allow claim 11 as amended subsequent to the final rejection, which are all of the claims pending in this application.[3]

[1] We note that the declaration (p. 2) has typed the "Full name of sole or first inventor" as "Lata Ramanthan" while the signature appears as "Lata Ramanathan."

[2] Application for patent filed July 7, 1994. According to appellants, this application is a continuation of application 07/859,689 filed June 11, 1992, now abandoned, which is the United States national application corresponding to international application no. PCT/US90/07289 filed December 18, 1990 under 35 U.S.C. § 371, now abandoned, which is a continuation-in-part of application no. 07/453,570 filed December 20, 1989, now abandoned.

[3] Entry of the amendment filed July 29, 1996 (Paper No. 23) amending claim 11 was authorized by the examiner in the supplemental examiner's answer (Paper No. 24, mailed October 16, 1996, p. 1).

Claim 11 is illustrative and reads as follows:

> 11. A method for producing antibodies which specifically bind to and inhibit the binding of human Interleukin-4 (IL-4) to receptors comprising administering to an animal a sufficient quantity of a polypeptide consisting of amino acid residues 61 to 82 of IL-4, wherein the animal produces antibodies against the polypeptide, said antibodies being able to specifically bind to human IL-4 and are able to inhibit the binding of human IL-4 to cellular receptors.

The references relied on by the examiner are:

Abrams et al. (Abrams)	5,013,824	May 7, 1991 (filed Sep. 19, 1986)

KÅhler et al. (Kohler), "Continuous cultures of fused cells secreting antibody of predefined specificity," Nature, Vol. 256, pp. 495-497 (August 7, 1975)

J. Goding, MONOCLONAL ANTIBODIES: PRINCIPLES AND PRACTICE, 2nd ed., pp. 198-199 (Academic Press, London, 1986)

ISSUES[4]

Claims 11 and 12 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Abrams. Claim 13 stands rejected under 35 U.S.C. § 103 as being unpatentable over Abrams, Kohler and Goding.

We reverse both rejections.

[4]The examiner changed the statutory basis of the final rejection of claims 11 and 12 originally made under 35 U.S.C. § 102(b) to a rejection under 35 U.S.C. § 102(e) and withdrew the final rejection of claim 13 under 35 U.S.C. § 103 over Abrams and Kohler in favor of a rejection over Abrams, Kohler and Goding (answer, p. 3).

In reaching our decision in this appeal we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper No. 20, mailed May 29, 1996) and to the examiner's supplemental answer (Paper No. 24, mailed October 16, 1996) for the examiner's reasoning in support of the rejections and to the appellants' brief (Paper No. 19, filed February 12, 1996) and to the appellants' reply brief (Paper No. 21, filed July 29, 1996) for the appellants' arguments thereagainst.

THE INVENTION

Human Interleukin-4 (IL-4) is protein which enhances the growth and/or biological activities of T and B lymphocytes, macrophages, mast cells and erythropoietin-stimulated red blood cell progenitors, as well as increases in IgG and IgE production. Antagonists of IL-4 may, therefore, be useful for treating allergies by decreasing mast cell growth and IgE production. Antibodies have been used to antagonize the biological activity of IL-4. See specification, p. 1, l. 14 - p. 2, l. 8.

The claimed invention is directed to a method of producing antibodies capable of binding to IL-4 and of inhibiting the binding of IL-4 to cellular receptors, which method comprises administering a polypeptide consisting of amino acid residues 61 to 82 of IL-4 to an animal whereby the animal produces the desired antibodies (claim 11).

According to the specification,

> [p]referably, the immunogenicity of the polypeptides is increased by combination with an adjuvant and/or by conversion to a larger form prior to immunization (p. 11, ll. 28-30)

or

> [t]he immunogenicity of the polypeptides can also be enhanced by cross-linking or by coupling to an immunogenic carrier molecule .... Cross-linking or conjugation to a carrier molecule may be required because small polypeptides sometimes act as haptens (molecules which are capable of specifically binding to an antibody but incapable of eliciting antibody production, i.e., they are not immunogenic). Conjugation of such polypeptides to an immunogenic carrier molecule renders the fragments immunogenic through what is commonly known as the "carrier effect." [P. 12, ll. 11-22.]

Production of the desired antibodies is determined using a two-part screening procedure, i.e., (1) an ELISA analysis using the immunizing polypeptide and IL-4 as antigens and (2) a radioligand receptor binding analysis which measures the inhibition of the specific binding of ^{125}I-IL-4 to cellular receptors (specification, p. 16, ll. 21-26).

The specification exemplifies immunizing rabbits by intradermal administration of a combination of polypeptide No. 7 (i.e., amino acid residues 61 to 82 of IL-4), pertussis vaccine and Freund's complete adjuvant (p. 21) and ELISA and radioligand analyses of the obtained antiserum (i.e., antiserum 343-6 IgG fraction) (pp. 22-24).

OPINION

All of the appealed claims require a method comprising administration of "a polypeptide consisting of amino acid residues 61 to 82 of IL-4" (emphasis added). The

transitional phrase "consisting of" excludes any elements, step, or ingredient not specified in the claim. See In re Gray, 53 F.2d 520, 521, 11 USPQ 255, 256 (CCPA 1931) and Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1949). Thus, while we interpret claim 11 as being open to the administration of other ingredients in addition to the recited polypeptide, e.g., an adjuvant, the recited polypeptide is limited to only the specified amino acid residues. The examiner has not pointed out, and we do not find where, Abrams discloses or suggests that antibodies can be elicited by administration of IL-4-derived polypeptides per se.[5] Rather, Abrams specifically discloses and exemplifies conjugating the polypeptide to an immunogenic carrier molecule (see e.g., c. 4, ll. 8-22; c. 8, ll. 31-33; EXAMPLES I-VIII). Moreover, Abrams fails to disclose or suggest that the carrier molecule can be deleted, e.g., replaced with an adjuvant to increase to the immunogenicity of the polypeptide. Therefore, in view of the amended claim language, we agree with appellants that claim 11 is not anticipated by Abrams because

> Abrams *et al.* have coupled the polypeptide Lys_{61} - Phe_{82} to myoglobin, while [in] the present invention the polypeptide is not coupled to anything (emphasis in the original, reply brief, p. 4, para. 1).

[5] Indeed, the examiner has failed to acknowledge or address appellants' argument that the polypeptide of amended claim 11 was not coupled to anything (see e.g., supplemental answer, p. 1, "Applicants' arguments [in the reply brief] in traversal of the art rejections are identical to those advanced in the Brief.").

The rejection of claims 11 and 12 under § 102(e) as anticipated by Abrams is reversed. Since the limitation of administration of "a polypeptide consisting of amino acid residues 61 to 82 of IL-4" is not disclosed or suggested by Kohler or Goding, the rejection of claim 13 under § 103 is not sustainable. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

OTHER MATTERS

We note that the three references, BV, BW and BX, listed on PTO-1449, page 5, of the Information Disclosure Statement filed August 6, 1992 in parent application 07/859,689, have not been either initialed or lined out by the examiner.

CONCLUSION

To summarize, the decision of the examiner to reject claims 11 and 12 under 35 U.S.C. § 102(e) as being anticipated by Abrams and to reject claim 13 under 35 U.S.C. § 103 as being unpatentable over Abrams, Kohler and Goding is reversed.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
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) BOARD OF PATENT

CAROL A. SPIEGEL	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
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DEMETRA J. MILLS	)	
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APPLICATION NO. 08/271,539

APJ SPIEGEL

APJ MILLS

APJ WINTERS

DECISION: **REVERSED**

Prepared By:

DRAFT TYPED: 26 Apr 02

FINAL TYPED: